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| 10/521,045   | 01/11/2005  | Daniel Rachlin       | 336-1102US          | 6611             |
| 23429 7590 03/18/2010<br>GREGORY SMITH & ASSOCIATES<br>3900 NEWPARK MALL ROAD, 3RD FLOOR<br>NEWARK, CA 94560 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| BOR, HELENE CATHERINE  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/521,045

## Applicant(s)

RACHLIN ET AL.

## Examiner

HELENE BOR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-21 is/are rejected.
- 7) ☒ Claim(s) 9, 10 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states, "solid, non-flowable hydrogel" and further dependent Claim 5 states, "mesh support structure". According to the Applicant's Specification the mesh support is to provide structural integrity and tear resistance (Page 8, Line 1-5). Based on the disclosure and the structure of the claims, it is entirely possible that a type of hydrogel would not be solid (poor structural integrity) or non-flowable (poor tear resistance) without the structural support of the mesh. The Examiner contends that it would be possible to have a scan window that would not meet Claim 1 without the structural support of Claim. That is, there appears to be two embodiments of the hydrogel: (a) hydrogel that is solid and non-flowable alone and (b) hydrogel that is solid and non-flowable by means of a mesh support. However, embodiment (b) to which claim 5 is directed does not recite a further limitation of embodiment (a), but rather improperly recites a limitation outside of the scope thereof.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 11, 13-14 & 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Crowley (US Patent No. 5,400,785).

**Claim 1 & 14:** Crowley teaches an interface device for use with an ultrasound imaging system having a scan head with at least one transducer (Figure 1, Element 11, 14 & 16). Crowley teaches the interface device being removably attachable to the scan head [insertable] (Col. 3, Line 13-18 and Col. 4, Line 66 – Col. 5, Line 6). Crowley teaches a reservoir with a proximal end and a distal end (Figure 1a, Element 14 & Figure 1, Element 16), said proximal end being open and shaped to allow the transducer to be inserted within said reservoir (Figure 1, Element 14), wherein said proximal end of said reservoir is configured to maintain a fluid tight seal between said reservoir and the scan head (Figure 1, Element 15 and Col. 3, Line 22-24), and wherein said distal end of said reservoir is configured to extend past a distal end of the transducer (Figure 2, Element 11 & 16). Crowley teaches a scan window located proximate said distal end of said reservoir through which ultrasound energy is transmitted and received (Figure 2, Element 11 & 13 and Col. 3, Line 13-18) wherein said scan window is formed of a solid, non-flowable hydrogel (Col. 1, Line 65-68 & Col. 4, Line 58-60). Crowley

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teaches a fluid tight seal between said scan window and said distal end of said reservoir (Figure 1, Element 15), and a fluid acoustic coupling medium located within said reservoir and filling a space between said transducer and said scan window (Col.3, Line 41-43 & Col. 4, Line 62-66). Crowley teaches emission is excess of 10 MHz (Col. 3, Line 48).

**Claim 2:** Crowley teaches wherein the interface device is sterile (Col. 3, Line 41-43).

**Claim 3:** Crowley fails to teach the specific properties of the hydrogel. However, Crowley teaches using gelatin, collagen or polyethylene oxide, which are hydrogels listed on Page 7, Lines 25-31. The same materials would inherently have the same properties such as less than 1dB/mm signal loss of transmitted and received high frequency ultrasound.

**Claim 11:** Crowley teaches wherein a distal surface of said scan window has a preformed concave curve to approximate a curvature (when viewed from the open end of the device) of an eye (Figure 1, Element 13a and Col. 5, Line 3-6).

**Claim 13:** Crowley teaches wherein the device incorporates delivery of the fluid acoustic coupling material to a distal surface of said scan window (Col. 2, Line 19-22 & 44-52)

**Claim 19:** Crowley teaches therein said proximal end of said reservoir is configured to allow the transducer to transverse across an intended scan path within said reservoir (Col. 3, Line 41-56).

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 4-8 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US Patent No. 5,400,785) as applied to Claim 1-3, 11, 13-14 & 19 above and further in view of Matthews (US Patent No. 3,939,123).

**Claim 4-7 & 21:** Crowley teaches the hydrogel comprises polyethylene oxide (Col. 1, Line 65-68). Crowley teaches a mesh [grid/matrices] support structure comprising a mesh of fibers [nylon] embedded in the hydrogel (Col. 4, Line 16-41). Crowley fails to teach cross-linked hydrogel. Matthews teaches wherein said cross-linked hydrogel comprises a cross-linked polymer with water content greater than or equal to 50% by weight (Col. 4, Line 68 – Col. 5, Line 6).

**Claim 8:** Crowley fails to teach the specific hydrogel composition. However Matthews teaches hydrogel formed from polyisocyanate terminated poly(alkylene ether) polyols (Col. 2, Line 13-49). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Crowley to include the hydrogel composition as taught by Matthews in order to produce a hydrogel with high water absorbency (Col. 5, Line 1-6) because high water content reduces attenuation as evidenced by Hayakawa; Col. 1, Line 57-59.

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7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US Patent No. 5,400,785) as applied to Claim 1-2, 11, 13-14 & 19 above and further in view of Paton et al. (US Patent No. 4,120,291).

**Claim 12:** Crowley teaches ultrasound welding or adhesive to secure the reservoir to the scan window. Crowley fails to teach mechanically securing. However, Paton teaches wherein the reservoir comprises a plurality of separate pieces between which said scan window is mechanically secured (Col. 3, Line 1-2) as an alternative expedient in the art of securing. It would have been obvious to one of ordinary skill in the art to use mechanical securing means as taught by Paton to modify the system of Crowley as an alternative expedient in the art of securing.

8. Claim 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US Patent No. 5,400,785) as applied to Claim 1-2, 11, 13-14 & 19 above and further in view of de Juan et al. (US Patent Application No. 2001/0029335 A1).

**Claim 15-17:** Crowleys fails to teach the surgical instrument or access for the surgical instrument. However, de Juan'335 teaches the device incorporating a surgical instrument and an entry aperture (Figure 5A, Element 305a & 206, Figure 6A & 6B and Page 4, Paragraph 0042). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the system of Crowley to include the surgical instrument and entry aperture as taught by de Juan in order for a surgeon to scan the retina during the procedure to

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evaluate the effectiveness of the action taken and for instrument introduced (Page 4, Paragraph 0042 & 0046).

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US Patent No. 5,400,785) as applied to Claim 1-2, 11, 13-14 & 19 above, and further in view of Katsumata (US Patent No. 5,078,149).

**Claim 18:** Crowley fail to teach sterilizing the interfacing device however, Katsumata teaches the interface device being sterile (Col. 5, Line 47-53) for use in surgical operations which require sterilization (Col. 5, Line 50-53). It would have been obvious to one of ordinary skill in the art to modify the system of Crowley to include the sterilization as taught by Katsumata for use in surgical operations which require sterilization (Col. 5, Line 50-53).

***Allowable Subject Matter***

10. Claims 9-10 & 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: Modification of Crowley to contain the claimed subject matter of Claims 9-10 & 22 would not be obvious as the modification of would destroy the Crowley reference. The Crowley reference is configured for use in various vessels of the body not for the configuration as claimed in Claims 9-10 & 22.

***Response to Arguments***

12. Applicant's arguments, see Page 8, filed 11/24/2010, with respect to the rejection(s) of claim(s) 1-19 under 35 U.S.C. § 103(a) have been fully considered



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and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Crowley (US Patent No. 5,400,785).

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./  
Examiner, Art Unit 3768

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

